

digitalis per tablet. The United States Pharmacopeia provides that the potency of digitalis calculated from the prescribed assay is satisfactory if the result is not less than 85 percent and not more than 120 percent of the labeled potency.

**LIBELED:** 3-14-56, Dist. Ariz.

**CHARGE:** 501 (b)—the strength of the article, when shipped, differed from the standard for such article as set forth in the U. S. Pharmacopeia; and 502 (a)—the label statement "Each Tablet Contains: Digitalis, U. S. P.—1½ gr." was false and misleading.

**DISPOSITION:** 4-30-56. Default—destruction.

**5172. Digitalis tablets.** (F. D. C. No. 39237. S. No. 37-667 M.)

**QUANTITY:** 12 1,000-tablet btls. and 2 500-tablet btls. at Buffalo, N. Y.

**SHIPPED:** 3-27-56, from St. Louis, Mo., by Keith-Victor Pharmacal Co.

**LABEL IN PART:** "Digitalis 1½ grs. Myocardial Stimulant Each tablet represents Digitalis Leaf 1 U. S. P. Unit \* \* \* Control 264-456 \* \* \* Manufactured for Kloman Inst. Co., Inc. Buffalo, New York."

**RESULTS OF INVESTIGATION:** The tablets were shipped in interstate commerce in bulk, and upon their receipt by the consignee, were repackaged and relabeled.

Analysis showed that the digitalis potency of the article fell below its professed potency.

**LIBELED:** 5-15-56, W. Dist. N. Y.

**CHARGE:** 501 (b)—the article purported to be and was represented as a drug, "Digitalis Tablets," the name of which is recognized in the United States Pharmacopeia, an official compendium, and, when shipped, its strength and quality differed from the standard set forth in such compendium; and 502 (a)—the label statement "Digitalis 1½ grs." was false and misleading.

**DISPOSITION:** 6-20-56. Default—destruction.

**5173. Thyroid tablets.** (F. D. C. No. 39598. S. No. 55-326 M.)

**QUANTITY:** 5 5,000-tablet btls. and 28 1,000-tablet btls. at Columbus, Ohio.

**SHIPPED:** 12-29-55, from Memphis, Tenn., by Morton Pharmaceuticals, Inc.

**LABEL IN PART:** "Code No. 467 \* \* \* Thyroid Tablets 1 Gr. Code No. 466 E. C. Orange Each Tablet Contains Thyroid 1 Gr. USP \* \* \* Distributed By Standard Medical Supply Co. \* \* \* Columbus, Ohio."

**LIBELED:** 10-17-56, S. Dist. Ohio.

**CHARGE:** 501 (b)—the article was represented as a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and, when shipped, it fell below the official standard of quality since it failed to comply with the U. S. P. disintegration test for tablets.

**DISPOSITION:** 11-21-56. Default—destruction.

**5174. Velestron tablets.** (F. D. C. No. 39447. S. No. 27-218 M.)

**QUANTITY:** 52 100-tablet btls. at Birmingham, Ala., in possession of Veltex Co.

**SHIPPED:** 2-29-56, from St. Louis, Mo., by Victor M. Hermelin & Co.

**LABEL IN PART:** (Btl.) "100 Tablets Velestron Conjugated Estrogens 1.25 Mg. \* \* \* Each Sugar-Coated Brown Tablet Contains: Naturally-occur-

ring water soluble, Conjugated Estrogens equivalent in biological activity to 1.25 Mg. of Sodium Estrone Sulfate."

**RESULTS OF INVESTIGATION:** The tablets were shipped in interstate commerce in bulk drums under an invoice reading, in part, as follows: "Conjugated Estrogens 1.25 Mg. S. C. yellow oval. Each tablet contains: Naturally occurring water-soluble, conjugated forms of the mixed estrogens obtained from the urine of pregnant mares. The principal estrogen present is Sodium Estrone Sulfate with varying small amounts of other equine estrogens and relatively large quantities of Nonestrogenic material."

Upon receipt of the drums, the consignee repackaged the tablets into bottles labeled as described above. Analysis showed that the total estrogen content per tablet was equivalent to not more than 0.92 mg. of sodium estrone sulfate.

**LIBELED:** 8-27-56, N. Dist. Ala.

**CHARGE:** 501 (c)—the strength of the article, when shipped and while held for sale, differed from that which it purported and was represented to possess, namely, an amount of estrogens in each tablet equivalent to 1.25 mg. of sodium estrone sulfate; and 502 (a)—while held for sale, the label statement "Each Sugar-Coated Brown Tablet Contains: Naturally-occurring water soluble, Conjugated Estrogens equivalent in biological activity to 1.25 Mg. of Sodium Estrone Sulfate" was false and misleading.

**DISPOSITION:** 9-27-56. Default—destruction.

**5175. Orapin tablets.** (F. D. C. No. 39282. S. Nos. 38-883/5 M.)

**QUANTITY:** 1 23,000-tablet btl., 109 100-tablet btl., and 6 500-tablet btl. at Sarasota, Fla., in possession of Still Co., Inc., t/a Stillco Laboratories.

**SHIPPED:** 2-25-55, from Brooklyn, N. Y.

**LABEL IN PART:** (Btl.) "No. 154 Orapin 0.300 mgm. Conjugated Estrogens," "No. 148 Orapin 0.625 mgm. Conjugated Estrogens," or "No. 146 Orapin 1.25 mgm. Conjugated Estrogens."

**RESULTS OF INVESTIGATION:** Analyses showed that the tablets contained conjugated estrogens equivalent to (No. 154) 0.21 mg., (No. 148) 0.39 mg., and (No. 146) 0.78 mg. of sodium estrone sulfate per tablet.

**LIBELED:** 7-2-56, S. Dist. Fla.

**CHARGE:** 501 (c)—the strength of the tablets, while held for sale, differed from that which they purported and were represented to possess; and 502 (a)—the label statements (No. 154) "Each tablet contains conjugated estrogens equivalent to 0.300 mgm. of Sodium Estrone Sulphate," (No. 148) "Each tablet contains conjugated estrogens equivalent to 0.625 mgm. of Sodium Estrone Sulphate," and (No. 146) "Each tablet contains conjugated estrogens equivalent to 1.25 mgm. of Sodium Estrone Sulphate" were false and misleading.

**DISPOSITION:** 9-20-56. Default—destruction.

**5176. Adhesive bandages.** (F. D. C. No. 39411. S. No. 28-701 M.)

**QUANTITY:** 2 ctns., each containing 49 boxes, at San Francisco, Calif.

**SHIPPED:** 12-28-55, from Buffalo, N. Y., by United States Plastic Bandage Co.

**LABEL IN PART:** (Box) "Contains 100 Bandages  $\frac{3}{4}$ " x 3" Elast Aids Pliable Plastic Bandages \* \* \* Sterility guaranteed—unless envelope opened."